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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,077	02/14/2001	Jonathan S. Stamler	1661 - CIP	9791

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	14

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/782,077	Applicant(s) STAMLER, JONATHAN S.	
	Examiner JOHN D PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11 and 13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-11,13-16 and 18-22* is/are rejected.

7)☒ Claim(s) *4,5 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-5, 7-11 and 13-22 are pending in this application.

Applicant is advised that should claim 19 be found allowable, claim 20 (identical to claim 19) will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The subject matter set forth in claims 21-22 were not reasonably conveyed in the originally filed disclosure. There is no indication from the originally filed disclosure that the H_2S will cause bronchial obstruction. This is new matter that is without adequate written descriptive support.

Claims 1-3, 7-9 and 14-15 stand rejected for the reasons of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific substances delivered as gases that have been identified in the specification (e.g., ethyl nitrite, NOH, NO-halogen, N_2O_3), does not reasonably provide enablement for other gases that have not been specifically disclosed. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive. At the outset, applicant is mistaken in asserting that "[I]t is not sufficient for the office action simply to say that other treating agents cannot be determined without undue experimentation." The previous Office action did not just make a conclusory statement of undue experimentation without support – rather, the previous Office Action has set forth all of the Wands factors and weighed the factors to determine that the scope of enablement is insufficient with respect to the non-specified gases. The Examiner has met his burden.

Applicant fails to account for the fact that the claimed invention is directed to treating patients with pulmonary disorders, i.e. patients who have bronchial obstruction, patients who have trouble breathing, patients who are under severe respiratory distress. There is not much room for experimenting with these patients. For example, mortality rate of ARDS and PPHN (persistent pulmonary hypertension of the newborn) is about 40% and up to 48%, respectively. It is against this backdrop that the Examiner has made a scope of enablement-based rejection. To such challenged patients applicant's invention administers a gas. This gas better work since time and effective treatment is of essence for such patients. One wrong move with these type of patients and the outcome is mortality or serious complications. Applicant has not identified the various other gases that are readable on the claimed invention. Therefore, based on a totality of factors, including the nature of the invention, the Examiner maintains the previous

finding that there would be undue experimentation in being able to determine other gases that have not been specified by the disclosure. See the full discussion of this issue in Paper No. 12, pages 2-5.

Claims 10-11 and 13-16, 18-20 are rejected for the reasons of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific substances delivered as gases that have been identified in the specification (e.g., ethyl nitrite, NOH, NO-halogen, N_2O_3), does not reasonably provide enablement for H_2S in the absence of further limiting features. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The basis for this ground of rejection is in the scope of the claims wherein H_2S is administered to patients with pulmonary disorders. But note, H_2S is an asphyxiant gas. It was already shown by the cited references in the previous Office Actions that administration of H_2S to asthmatic patients would be detrimental. Clearly, from the cited references on page 3 of Paper No. 6 (10/31/02), one skilled in the art would not administer H_2S to asthmatics **or** other patients with pulmonary disorders and respiratory distress. Toxcenter accession no. 2002:618658 discloses that hydrogen sulfide is an asphyxiant gas, which at high doses has the same effect as high doses of cyanide; 100-150 ppm inhalation results in irritation; 900 ppm causes serious systemic effects in less than 30 minutes and death in 1 hour; is known to cause pulmonary edema; and earliest toxic response in occupation settings is 10.5 ppm. "*When inhaled, hydrogen sulfide*

exerts an irritant action throughout the entire respiratory tract, although the deeper structure suffer the greatest damage."

Against this state of the art about an asphyxiant gas, applicant would administer the same asphyxiant H_2S gas to the bronchially challenged and distressed patients. Note, claims 10-11 are open to 100 ppm H_2S, and claims 14-16 are without specific limits as to concentration of H_2S. One skilled in the art would be faced with undue experimentation in obtaining the claimed therapeutic results. Applicant's specification Example X is noted in this regard, but the claims are nowhere commensurate in scope with the tightly controlled treatment protocol that produced such result.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive. Applicant argues that H_2S as an asphyxiant gas is an overgeneralization. Again, applicant fails to take into account the fact that the claims call for administering such a gas to already-challenged individuals such as those with asthma, lung injury, cystic fibrosis, hypoxemia, pulmonary hypertension, ARDS or pneumonia. These patients have trouble breathing. They often face fatal outcomes without effective intervention. An asphyxiating gas should not be administered to such patients unless applicant can come up with sufficiently circumscribed set of parameters to ensure effective treatment.

Applicant argues that "therapeutically effective" amount language suffices because this excludes harmful amounts. Applicant also argues that 0.1-100 ppm H_2S in nitrogen is distinguishable because it is less likely to be oxidized to sulfuric acid. These arguments are not persuasive. The Examiner maintains that for respiratory distressed

patients such as for example, patients with ARDS and newborns with PPHN, determination of such effective amount would require undue experimentation in the absence of sufficient claim language to carefully circumscribe the protocol. Applicant's evidence and claim language fail to overcome the problems associated with administering H_2S to seriously challenged patients with pulmonary disorders such as persistent pulmonary hypertension of the newborn, ARDS, pneumonia, interstitial lung disease such as pulmonary fibrosis and cystic fibrosis.

Claims 4-5 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PAK whose telephone number is (703)308-4538. The examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600